

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number: TM-06-06-FR]

RIN 0581-AC60

National Organic Program – Revisions to Livestock Standards Based on Court Order
(Harvey v. Johanns) and 2005 Amendment to the Organic Foods Production Act of 1990
(OFPA)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule revises the National Organic Program (NOP) regulations to comply with the final judgment in the case of Harvey v. Johanns (Harvey) issued on June 9, 2005, by the U.S. District Court, District of Maine, and to address the November 10, 2005, amendment made to the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq., the OFPA), concerning the transition of dairy livestock into organic production.

Further, this final rule revises the NOP regulations to clarify that only nonorganically produced agricultural products listed in the NOP regulations may be used as ingredients in or on processed products labeled as “organic.” In accordance with the final judgment in Harvey, the revision emphasizes that only the nonorganically produced agricultural ingredients listed in the NOP regulations can be used in accordance with any specified restrictions and when the product is not commercially available in organic form.

To comply with the court order in Harvey, USDA is required to publish final revisions to the NOP regulations within 360 days of the court order, or by June 4, 2006.

Accordingly, this final rule amends the NOP regulations to eliminate the use of up to 20 percent nonorganically produced feed during the first 9 months of the conversion of a whole dairy herd from conventional to organic production. This final rule also addresses the amendment made to the OFPA concerning the transition of dairy livestock into organic production by allowing crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management to be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products.

DATES: Effective June 8, 2006 except for § 205.606, which is effective June 9, 2007.

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SUPPLEMENTARY INFORMATION:

I. Background

In 1990, Congress passed the OFPA, which required the USDA to develop national standards for organically produced agricultural products to assure consumers that agricultural products marketed as organic meet consistent, uniform standards. Based on the requirements of the OFPA, USDA established the NOP to develop national organic standards, including a National List of substances approved for and prohibited from use in organic production and handling, that would require agricultural products labeled as organic to originate from farms or handling operations certified by a State or private entity that has been accredited by USDA. On December 21, 2000, USDA published the

final rule for the NOP in the Federal Register (7 CFR Part 205). On October 21, 2002, the NOP regulations became fully implemented by USDA as the uniform standard of production and handling for organic agricultural products in the United States.

In October 2003, Arthur Harvey filed a complaint under the Administrative Procedure Act in the U.S. District Court, District of Maine. Mr. Harvey alleged that several subsections of the NOP regulations violated OFPA, were arbitrary, and not in accordance with law.

On January 26, 2005, the U.S. Court of Appeals for the First Circuit issued a decision in the case. The court upheld the NOP regulations in general, but remanded the case to the U.S. District Court, District of Maine, for, among other things, the entry of a declaratory judgment that stated 7 CFR 205.606 does not establish a blanket exemption to the National List requirements specified in 7 U.S.C. 6517, permitting the use of nonorganic agricultural products in or on processed organic products when their organic form is not commercially available. The district court ordered the Secretary to make publicly known within 30 days – through notice in the Federal Register to all certifying agents and interested parties -- that 7 CFR 205.606 shall be interpreted to permit only the use of a nonorganically produced agricultural product that has been listed in 7 CFR 205.606 pursuant to National List procedures, and when a certifying agent has determined that the organic form of the agricultural product is not commercially available. USDA complied with this order on July 1, 2005 (70 FR 38090).

The court also ruled in favor of Mr. Harvey with respect to 7 CFR 205.605(b) of the NOP regulations, concerning the use of synthetic substances in or on processed products which contain a minimum of 95 percent organic content and are eligible to bear

the USDA seal (7 CFR 205.605(b)). The court found § 205.605(b) contrary to the OFPA and in excess of the Secretary's rulemaking authority.

In addition, the court found in favor of Harvey with respect to 7 CFR 205.236(a)(2)(i) of the NOP regulations. This section creates an exception to the general requirements for the conversion of whole dairy herds to organic production. The court found the provisions at 7 CFR 205.236(a)(2)(i) contrary to the OFPA and in excess of the Secretary's rulemaking authority.

On June 9, 2005, the district court issued its final judgment and order in the case. A copy of the final judgment and order may be found at <https://www.ams.usda.gov/nop>.

Congressional Amendment to the OFPA

After the court issued its final judgment and order, Congress amended the OFPA. On November 10, 2005, Congress amended the OFPA by permitting the addition of synthetic substances appearing on the National List for use in products labeled "organic." The amendment restores the NOP regulation for organic processed products containing at least 95 percent organic ingredients on the National List and their ability to carry the USDA seal. Therefore, USDA is not revising the NOP regulations to prohibit the use of synthetic ingredients in processed products labeled as organic nor restrict these products' eligibility to carry the USDA seal.

Congress also amended the OFPA to allow a special provision for transitioning dairy livestock to organic production. The NOP regulations currently provided that when an entire, distinct herd is converted to organic production, the producer may, for the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with

organic crop requirements. The circuit court found these provisions to be contrary to the OFPA and in excess of the Secretary's rulemaking authority.

In the amendments to OFPA, Congress provided a new provision to allow crops and forage from land included in the organic system plan of a farm that is in the third year of organic management to be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products. USDA is revising § 205.236(a)(2) to reflect this amendment to the OFPA in this rulemaking.

II. Comments Received

We received 13,115 comments, most as form letters (13,020). Comments were received from consumers, producers, processors, trade associations, food industry organizations, certifying agents, the National Organic Standards Board (NOSB), and state governments. The majority of the comments received dealt with the proposed changes to the dairy animal language in the regulation.

Several comments requested a more lengthy comment period than the 15-day comment period provided. However, the Department determined that the changes that were mandated by the U.S. District Court to be completed by June 4, 2006, had been well publicized for over a year, as the circuit court's decision was published on January 26, 2005. To meet the mandated court deadline therefore, a shortened comment period was considered appropriate.

Comments were received dealing with paragraph § 205.606 and how commercial availability and the National List procedures applies to products labeled as "made with organic (ingredients)." This was an error in the proposed rule; paragraph § 205.606 should only pertain to products labeled as "organic." Because products labeled as "made

with organic (ingredients)” may, by definition, contain up to 30 percent nonorganic agricultural ingredients, regardless of commercial availability, we have corrected the language in this final rule.

Commenters requested that changes be made to § 205.600(b), dealing with the criteria by which materials are evaluated by the National Organic Standards Board (NOSB) for inclusion on the National List. Specifically, commenters asked to eliminate the words “processing aids and adjuvants” in the criteria of synthetics to be reviewed of handling materials under § 205.600(b). The Department has no position on this comment at this time, as the comments go beyond the scope of the proposed rule. These comments will be provided to the NOSB and the NOSB may consider whether to make a recommendation to the Department for amending the NOP regulations.

Other commenters discussed the definitions of the terms “ingredient,” “processing aid,” and “substance.” These commenters suggested that changes in the NOP regulations section of definitions, or elimination of some words altogether elsewhere in the NOP regulations, could improve the clarity of the NOP regulations with respect to how materials are evaluated for inclusion on the National List.

In response to the commenters’ suggestions to improve the clarity of the NOP regulations by revising aforementioned terms, the Department welcomes these suggestions. However, these comments will be provided to the NOSB for consideration of a recommendation to the Department for amending the NOP regulations through future notice and comment rulemaking. As noted above, this rulemaking seeks merely to satisfy the court final order and judgment and implement the Congressional amendments at this time.

We also received several comments related to the amendment to the OFPA by Congress that authorized the Secretary to establish procedures for adding nonorganic agricultural materials to the National List in the event of an emergency if they are commercially unavailable in organic form. These commenters asked for a 60-day notice and comment rulemaking period; commenters also asked when and how the Department planned to proceed with such rulemaking. Since this amendment to the OFPA is not part of this rulemaking, the Department will proceed through normal notice and comment rulemaking procedures and consult with the NOSB prior to publishing a proposed rule on emergency petition procedures.

The vast majority of the comments received dealt with subparagraph § 205.236(a)(i). Most comments were positive for keeping the last third of gestation for conversion of an entire dairy herd in the regulation. However, these commenters wanted the last third of gestation clause to apply to all dairy operations once the operation is certified as organic, regardless of the number of animals converted, or whether an entire, distinct herd is converted.

When Congress amended the OFPA, only the feed provision was addressed, to provide a different method of transition for dairy animals entering organic production. This final rule implements the Congressional amendments and the court's final judgment. USDA recognizes that this change still leaves two methods of replacement of dairy animals for organic dairy operations and that this is a matter of concern in the organic community. To address the issue of dairy replacement animals for all certified organic dairy operations, USDA will draft an advanced notice of proposed rulemaking (ANPR) to

invite public comment on further changes necessary to the NOP regulations dealing with the origin of dairy livestock under subparagraph § 205.236(a)(2), Dairy Animals.

We received comments that expressed concern that producers would be able to feed dairy animals feed and forage that had been harvested earlier than the third year, from land in transition to organic and that a certifying agent must be able to inspect the records to verify that this does not occur. This is a valid concern, and commas have been inserted in the final regulation to make clear that crops and forage must come from land that is in the third year of transition to organic.

III. Related Documents

Documents related to this final rule include the OFPA, as amended, (7 U.S.C. 6501 et seq.), its implementing regulations (7 CFR part 205), and a Federal Register notice publishing the final judgment and order in the case of Harvey v. Johanns (70 FR 38090).

A. Executive Order 12866.

This action has been determined not significant for purposes of Executive Order 12866, and therefore, does not have to be reviewed by the Office of Management and Budget.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under section 2115 of the OFPA (7 U.S.C. 6514) from creating programs of accreditation for private persons or State

officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in Sec. 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under Sec. 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspections Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act and Paperwork Reduction Act.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the Agricultural Marketing Service (AMS) performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this action on small entities and has determined that this final rule would have an impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration

(SBA) (13 CFR 121.201) as those having annual receipts of less than \$6,500,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

The U.S. organic industry at the end of 2001 included nearly 6,949 certified organic crop and livestock operations. These operations reported certified acreage totaling just over 2 million acres of organic farm production. Data on the numbers of certified organic handling operations (any operation that transforms raw product into processed products using organic ingredients) were not available at the time of survey in 2001; but they were estimated to be in the thousands. Based on 2003 data, certified organic acreage had increased to 2.2 million acres. By the end of 2004, the number of certified organic crop, livestock, and handling operations totaled nearly 11,400 operations, based on reports by certifying agents to NOP as part of their annual reporting requirements. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

U.S. sales of organic food and beverages have grown from \$1 billion in 1990 to an estimated \$12.2 billion in 2004. Organic food sales are projected to reach nearly \$15 billion for 2005. The organic industry is viewed as the fastest growing sector of agriculture, representing 2 percent of overall food and beverage sales. Since 1990, organic retail sales have historically demonstrated a growth rate between 20 to 24 percent each year. This growth rate is projected to decline and fall to a rate of 5 to 10 percent in the future.

In addition, USDA has accredited 96 certifying agents who have applied to USDA to be accredited in order to provide certification services to producers and

handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

Impact of Lawsuit and Congressional Amendment on Dairy

The loss of the 80-20 feed exception can be measured depending on various feed costs, for average farm sizes, and for the sector as a whole using 2003 estimates of the number of certified dairy livestock in the United States -- the latest year for which numbers are available.¹ Generally, for organic dairy operations, feed and labor are the most significant cost components, comprising upwards of 50 percent of the total variable costs of the operation.² Organic feed is significantly more expensive than conventional feed, and various quotes for organic feed run as high as double the cost of conventional or nonorganic feed rations. According to one study, higher feed cost was the largest and most important difference between organic and nonorganic dairy production, with the additional expense of feeding organic dairy costs being 54 percent of the price differential received for organic milk³. In this study, for a 48-cow organic herd, purchased feed cost \$1,003 per cow, or \$298 per cow more than for a conventional dairy operation. For the entire year, the average farm spent approximately \$49,000 for purchased organic feed for the 48-cow herd in this study.

¹ Greene, Catherine. Certified organic livestock, 2003, numbers were obtained from the author on permission; forthcoming from the Economic Research Service (ERS), U.S. Department of Agriculture.

² Dalton, Timothy J., Lisa A. Bragg, Rick Kersbergen, Robert Parson, Glenn Rogers, Dennis Kauppila, Qingbin Wang. "Cost and Returns to Organic Dairy Farming in Maine and Vermont for 2004," University of Maine Department of Resource Economics and Policy Staff Paper #555, November 23, 2005.

³ Ibid.

A rough estimate of the loss of the 80-20 feed exception can be determined using this study's farm cost numbers. Using the estimated per-cow feed numbers, if a dairy farmer had to switch from using 80 percent organic feed to 100 percent organic feed, and purchased all of the organic feed, the additional cost to the dairy farmer is \$27 per month, or about 2.7 percent higher than using the 80-20 feed exception.

For the sector, based on ERS's latest estimate of approximately 74,435 certified dairy cows in 2003, the loss of the 80-20 feed provision using the above cost estimates would amount to around \$2 million. But this assumes: (1) all of the dairy cows in the sector are converted to organic in the same year; (2) all farm operators use the 80-20 feed provision in that same year; and (3) all organic feed was purchased. Because these assumptions are unlikely, the \$2 million estimated for the sector likely overstates the total cost of the loss of the 80-20 feed provision. This cost estimate more likely represents an upper bound estimate based on this farm study's feed cost estimate, as if all dairy cows were converted to organic at a single point in time under the above assumptions.




Table 1. Cost of Losing 80-20 Feed Provision
Based on Vermont-Maine Dairy Study Cost Estimates

Organic feed per cow	\$1,003 per year or \$84 per month
Nonorganic feed per cow	795 per year or \$66 per month
9 months: 20% nonorganic feed cost:	$(0.2)*(\$66)*(9) = \119
80% organic feed costs:	$(0.8)*(\$84)*(9) = \605
3 months: 100% organic feed:	$(1.0)*(\$84)*(3) = \252
Total Feed Using 80-20	\$976
12 months using organic feed only:	12 months*\$84/cow = \$1,003
Difference (loss) of 80-20, 48-cow herd	12 mo*\$27/cow loss = \$1,296

Instead, an alternative estimate could be derived for a growing industry that is adding new dairy cows to the industry. According to ERS, in 2000, there were just over 38,000 certified dairy livestock, increasing to nearly 49,000 by 2001, and 67,000 in 2002. With reports of rising milk prices and shortages in the U.S. organic dairy market in 2005, continued growth in organic dairy livestock numbers could be expected.

Therefore, an alternative estimate of the loss is to calculate the number of dairy cows added to the sector each year and assume they were all added to the sector by being converted using the 80-20 feed transition provision. Using the ERS numbers above, between 2000 and 2001, 11,000 certified dairy cows were added. Another 18,000 cows were added by 2002, and 7,435 in 2003. On average, 12,145 dairy cows were added each year since 2000. Based on these numbers from ERS and the additional cost of \$27 per cow from the study above, using the 80-20 feed provision, the loss of the 80-20 provision would have cost dairy farmers approximately \$327,915 per year, or nearly \$1 million over the 3-year period.

Different estimates were obtained from discussions with Western state industry experts in dairy feed and nutrition, and budgets developed by certifying agents who work with certified dairy operations.⁴ These estimates resulted in higher costs due to the loss of the 80-20 feed provision, of as much as \$416 per cow annually, or assuming an addition of approximately 12,000 cows per year to the sector, a loss of nearly \$5 million per year to the sector.

Depending on location, climate, size, and purchased feed, costs may vary considerably. The west, for example, tends to be a feed-deficit region where farmers purchase more feed and rely less on feed from on-farm or nearby sources. The farther the distance a farmer has to go to obtain feed, the more costly the feed will be, all other things being equal, making it likely that costs would vary by region or climate.

With higher milk prices, more farmers might be attracted to enter organic dairy farming. In the short run, this would add to pressure (due to more competition) on feed supplies. With the loss of the 80-20 feed provision, this could drive up the cost of feed; in the short run, therefore, there could be additional upward pressure on these cost estimates.

Regardless, these additional costs would have to be absorbed somewhere. They must either be passed forward to consumers in the form of higher fluid milk and dairy product prices -- already at high premiums relative to conventional dairy product prices -- or they would have to be absorbed by farmers.

However, Congress did amend OFPA for transitioning dairy farmers, by permitting such dairy farmers to graze dairy livestock on land being converted to organic

⁴ Information provided in conversations with Pacific Nutrition-Consulting (PNC) based on USDA-ACA budgets for estimating the cost of the transition year for dairy farmers using the 80-20 feed provision.

production during its 3rd year of transition. Thus, the loss of the 80-20 feed exception is mitigated in part by the action that Congress took. In effect, a farm transitioning its dairy cows to organic could put its cows on that farm's pasture being converted to organic and the milk from those cows would be organic at the same time as crops being harvested from that land -- at the end of the third year that the land completed organic management.

Congress leveled the playing field for dairy farmers when they amended OFPA in this area by removing any penalties that dairy farmers faced with the so-called "4th year" – i.e., the additional transition year that dairy cows underwent due to lactation cycles. And Congress did not change the basic requirement of OFPA. Dairy cows must be organically managed for at least 12 months; after these 12 months of organic management, only her milk and milk products may be represented as organic.

The status of the dairy cow is a different story. The dairy cow is only organic if she was raised organically from the last third of the mother's gestation. When a dairy cow is slaughtered, she cannot be sold as organic slaughter stock unless she was raised organically from the last third of the mother's gestation, the same as other slaughter livestock (except poultry, which must be raised organically beginning with the second day of life). That remains the same in the NOP regulation.

In providing the transition language, entry in organic dairying may become easier, which could ease current milk shortages in the organic milk market at retail. Certainly it should help smaller dairy farmers entering the organic industry who may be faced with having to purchase higher priced organic feed, by allowing them to graze dairy livestock on their land that is being transitioned to organic certification.

Other changes in this rule merely implement Congressional amendments and the court's final judgment and order. With respect to alternatives to this rule, as stated above, this rule merely implements language which Congress has enacted and complies with the court's final judgment and order.

AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

No additional collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by § 305(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, et seq., or OMB's implementing regulation at 5 CFR part 1320.

Further, given the Congressional amendments, and the court's final judgment and order, good cause exists under 5 U.S.C. 533 for not postponing the effective date of this rule, except section § 205.606, until 30 days after publication in the Federal Register. List of Subjects in 7 CFR Part 205.

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, is amended as follows:

PART 205 - NATIONAL ORGANIC PROGRAM

The authority citation for 7 CFR part 205 continues to read as follows:

1. Authority: 7 U.S.C. 6501-6522.
2. Section 205.236 (a)(2) is revised to read as follows:

§ 205.236 Origin of Livestock.

(a)* * *

(2) Dairy animals. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, Except,

(i) That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products; and

(ii) That, when an entire, distinct herd is converted to organic production, the producer may, provided no milk produced under this subparagraph enters the stream of commerce labeled as organic after June 9, 2007: (a) For the first 9 months of the year, provide a minimum of 80-percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and (b) Provide feed in compliance with § 205.237 for the final 3 months.

(iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.

* * * * *

3. Section 205.606 is revised to read as follows:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients
in or on processed products labeled as organic.

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

- (a) Cornstarch (native)
- (b) Gums - water extracted only (arabic, guar, locust bean, carob bean)
- (c) Kelp - for use only as a thickener and dietary supplement
- (d) Lecithin - unbleached
- (e) Pectin (high-methoxy)

* * * * *

Dated:

Lloyd C. Day, Administrator
Agricultural Marketing Service